

FDA Adverse Reaction Reporting System for Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)

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FDA's Reporting Requirement: 21 CFR Part 1271.350-Effective May 25, 2005

- Manufacturers must ***investigate***:
 - ***Any*** adverse reaction involving a ***communicable disease*** related to an HCT/P that they made available for distribution.
 - Manufacturers must ***report*** to FDA
 - An adverse reaction involving a communicable disease if it:
 - Is fatal
 - Is life-threatening
 - Results in permanent impairment of function or permanent damage to body structure; or
 - Necessitates medical or surgical intervention, including hospitalization
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FDA's Reporting Requirements

- *Adverse reaction* means a noxious and unintended response to any HCT/P for which there is a reasonable possibility that the HCT/P caused the response
- To report adverse reactions, manufacturers must submit a MedWatch 3500A to FDA within 15 days of receipt of information
- And submit follow-up MedWatch report within 15 days of receipt of new information from the investigation



How are Adverse Reactions Reported to FDA?

- For **Manufacturers**:
 - Use Form **FDA 3500A** (MedWatch)
 - Report w/in 15 days of receipt of information
 - For **Voluntary** reporters:
 - Use Form **FDA 3500** (MedWatch)
 - Also promptly report to HCT/P establishments
 - FDA MedWatch reporting system
 - <http://www.fda.gov/medwatch>
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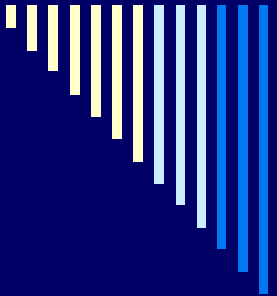
What Information to Include on MedWatch Report

- Specific name and type of product used
 - Recipient outcomes (symptoms, medical or surgical interventions, recovery, morbidity, death)
 - Indicators that adverse reaction was related to a communicable disease
 - Relevant dates
 - Results of cultures and other relevant studies
 - Devices implanted
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What Information to Include on MedWatch Report (cont.)

- Special handling/prep of product at implanting facility
 - Confirmation that donor met eligibility requirements and HCT/P met release criteria
 - Recipient risk factors for infection
 - If other recipients of donor tissue had adverse reactions (review of complaint file)
 - Impression of likelihood that adverse reaction was related to product (reasonable possibility)
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Other Information to Review in Investigation and Make Available to FDA if Requested

- Donor screening records
 - Did any deviations from facility's SOP occur in donor tissue processing
 - Copies of pre- and post-processing cultures of donor tissue
 - Copies of relevant recipient culture, serology, pathology and imaging results, clinic and operative notes
 - Copies of culture results from other recipients of donor's tissue
 - Results of hospital infection control investigation, if applicable
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Common Problems with MedWatch Reports

- Manufacturer reporting on voluntary form (3500) instead of mandatory form (3500A)
 - Reporting of device information in product section (and the reverse)
 - Insufficient information about the adverse reaction
 - Reporting of product problems when product was not implanted
 - Failure to submit a follow-up report
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U.S. Food and Drug Administration



CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

CONTACT INFORMATION

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